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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,127	07/30/2001	William J. Curatolo	PC10754AJTJ	1383

7590

07/15/2003

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/918,127

Applicant(s)

CURATOLO ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 and 19-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17, 18 and 35-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Examiner acknowledges receipt of IDS, request for extension of time and amendment B filed 04/25/03.

Examiner withdraws the indication that claims would be allowable if the limitations of claims 51 or 52 are incorporated in the generic claims because the prior art, Sikorski teaches a composition that comprises CETP inhibitor and hydroxypropylmethyl cellulose.

Claim Rejections - 35 USC § 112

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 49-55 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 49 and 50 recite the term "cellulosic."

Regarding claims 49 and 50, the term "cellulosic" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "cellulosic"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Applicants argue that the term "cellulosic" is definite and that Marriam –Webster's Collegiate Dictionary defines the term. Although, the term is defined, "cellulosic" imparts cellulose-type and the cellulose materials/polymer encompassed by the term cannot be ascertained. It is respectfully suggested that the affected claims recite cellulose polymer.

Art Unit: 1615

3. Claims 89-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 89-96 are vague and indefinite because they depend from claim 100, which does not exist. These claims are not examined since the claim they depend from is non-existent.

Correction is required

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-10, 17, 18, 35-51, 56-86 and 88 rejected under 35 U.S.C. 102(b) as being anticipated by Sikorski (WO 99/14204 cited by applicants in the disclosure and on the IDS filed 07/30/01).

Sikorski teaches a composition comprising cholesteryl ester transfer protein (CETP) inhibitor (page 4, line 30 to page 12 and line 19) and one or more non-toxic pharmaceutically acceptable carriers (page 80, line 4). On page 84, lines 27-29, Sikorski teach that CETP inhibitors are formulated as dispersions in hydroxypropylmethyl cellulose. Solutions and suspensions of the formulation can be prepared from sterile powders (page 84, lines 32 and 33). The active compound, which is the cholesteryl ester transfer protein inhibitor can be combined with one or more adjuvants and cellulose alkyl esters and polyvinylpyrrolidone are examples (page 84, lines 16-32). The formulation of Sikorski can be administered orally, intravascularly, intraperitoneally, subcutaneously, intramuscularly, topically (page 80, lines 11-14) and also to the eye (page 84, lines 8-15). The compounds of Sikorski, the CETP's, are useful for human

Art Unit: 1615

treatment, veterinary treatment, exotic and farm animal treatment (mammals, rodents, horses, dogs and cats) and the CETP's are useful in the treatment of dyslipidemia, coronary artery disease, atherosclerosis and coronary artery diseases (page 6, lines 2-20). Sikorski also discloses how to measure CETP activity *in Vitro* (page 71, line 14 to page 72 line 21) and inhibition of CETP activity is also tested *in Vivo* (page 72, line 23 to page 74 line 13).

Since pharmaceutical formulation of the CETP's can be in the form of tablet, capsule, suspension or liquid, the gastrointestinal tract is a use environment. Instant claims 35- 48 and 56-73 recite the properties of the pharmaceutical composition and how the composition is made instant claim 86 is not critical in a composition claim.

Sikorski meets the limitations of the claims.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 52-55 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sikorski (WO 99/14204).

Sikorski clearly teaches the teaches the composition of the instant claims except that Sikorski does not teach the concentration enhancing polymers recited in claims 52-55.

Regarding claim 87 spray drying technique for the preparation of the formulation is recited, it is respectfully submitted that spray drying is one of the processes of forming tablets. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of Sikorski that comprises CETP and hydroxypropymethyl cellulose.

Art Unit: 1615

One having ordinary skill in the art would have been motivated to substitute one concentration-enhancing polymer with another with the expectation that the concentration of the CETP will be enhanced.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
July 11, 2003

